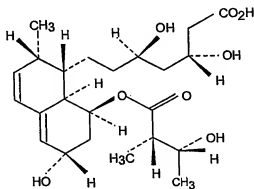
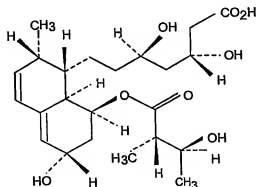


We claim:

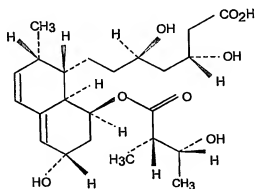
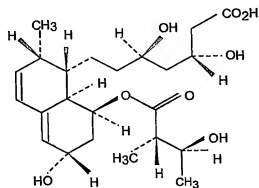
- 1 1. A process for producing substantially pure pravastatin, the process comprising
2 culturing microorganisms under conditions capable of converting compactin to
3 pravastatin by maintaining a concentration of compactin not less than 300 µg/mL
4 during the process.
- 1 2. The process of claim 1, wherein the culturing of microorganisms comprises
2 fermentation.
- 1 3. The process of claim 2, wherein the fermentation comprises a repeated fed-batch
2 culture technique.
- 1 4. The process of claim 2, further comprising periodically adding quantities of
2 compactin during the fermentation to maintain the concentration of compactin at
3 not less than 300 µg/mL during the process.
- 1 5. The process of claim 4, wherein the concentration of compactin is maintained
2 within the range of about 300-900 µg/mL.
- 1 6. The process of claim 4, wherein the compactin is in the form of a solution.
- 1 7. The process of claim 4, wherein the compactin comprises any soluble salt of
2 compactin.
- 1 8. The process of claim 7, wherein the compactin solution comprises the sodium salt
2 of compactin.
- 1 9. The process of claim 1, wherein the microorganism belongs to the *Streptomyces*
2 genus.
- 1 10. The process of claim 9, wherein the microorganism is a *Streptomyces carbophilus*
2 strain, variant or mutant thereof.
- 1 11. The process of claim 10, wherein the microorganism is a *Streptomyces carbophilus*
2 strain.

- 1 12. The process of claim 1, wherein the conditions capable of converting compactin to
2 pravastatin comprise a fermentation production medium comprising glucose at a
3 concentration of about 15-23 (g/L), Soya bean meal at a concentration of about 25-
4 38 (g/L), cottonseed meal at a concentration of about 2-4 (g/L), corn steep liquor at
5 a concentration of about 5-8 (g/L), sodium chloride at a concentration of about 5-6
6 (g/L) and calcium carbonate at a concentration of about 2-3 (g/L).
- 1 13. The process of claim 12, wherein the conditions capable of converting compactin
2 to pravastatin further comprise maintaining the temperature of the production
3 medium at about 18 °C to about 50°C.
- 1 14. The process of claim 13, wherein the temperature is maintained at about 25 °C to
2 about 30°C.
- 1 15. The process of claim 12, wherein the conditions capable of converting compactin
2 to pravastatin further comprise maintaining pH of the production medium at about
3 5 to about 10.
- 1 16. The process of claim 15, wherein the pH is maintained at about 6 to about 8.5.
- 1 17. The process of claim 15, wherein the pH is maintained at about 7.3 to about 8.0.
- 1 18. The process of claim 12, wherein the conditions capable of converting compactin
2 to pravastatin further comprises agitation at about 100 to about 600 rpm.
- 1 19. The process of claim 18, wherein the agitation is at about 100 to about 350 rpm.
- 1 20. The process of claim 1, wherein at least 50% w/w of compactin is converted to
2 pravastatin as determined by HPLC.
- 1 21. The process of claim 20, wherein the percentage conversion is at least about 65 to
2 about 75% w/w.
- 1 22. The process of claim 20, wherein the percentage conversion is at least about 70%
2 w/w.

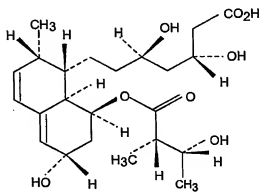
- 1 23. Substantially pure pravastatin containing not more than about 0.12% w/w of the
2 compound of Formula III and not more than about 0.6% w/w of 3"-hydroxy-
3 pravastatin of the structure of Formula IV.

**FORMULA III****FORMULA IV**

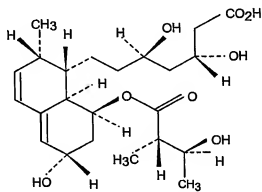
- 1 24. A pharmaceutical composition comprising substantially pure pravastatin, not more
2 than about 0.12% w/w of the compound of Formula III, not more than about 0.6%
3 w/w of 3"-hydroxypravastatin of the structure of Formula IV, and
4 pharmaceutically acceptable excipients.

**FORMULA III****FORMULA IV**

- 1 25. A method of treating hypercholesterolemia comprising administering to a patient
2 in need of treatment for hypercholesterolemia a pharmaceutical composition
3 comprising substantially pure pravastatin, not more than about 0.12% w/w of the
4 compound of Formula III, not more than about 0.6% w/w of 3"-hydroxy-
5 pravastatin of the structure of Formula IV, and pharmaceutically acceptable
6 excipients.



FORMULA III



FORMULA IV